Notice of Allowability	Application No.	Applicant(s)	
	09/744,169	JEARY ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment filed 11/07/07*.

2. ☒ The allowed claim(s) is/are *47-51,55-57 and 73-76*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *01/23/08* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peter Mlynek on 01/18/08.

The application has been amended as follows:

Claims 1, 4, 5, 20, 23, 24, 26, 28-30, 33, 34, 36-40, 45, 59-61, 67-72 and 77-81 have been cancelled.

Claim 47, line 13, after the phrase "oral administration", the word "and" has been deleted.

Claim 47, last line, after the phrase "that is different from the first amount", the phrase "and wherein the fluvoxamine release rate from the composition exhibits the flowing *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 15% of the total fluvoxamine is released after 0.5 of an hour of measurement in the apparatus;

(b) no more than about 25% of the total fluvoxamine is released after 1 hour

of measurement in the apparatus;

(c) between about 20% and about 75% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(d) not less than about 75% of the total fluvoxamine is released after 4 hours of measurement in the apparatus; and

(e) not less than about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus" has been inserted.

Claim 57, line 12, after the phrase "oral administration", the word "and" has been deleted.

Claim 57, last line, after the phrase "that is different from the first amount", the phrase "and wherein the fluvoxamine release rate from the composition exhibits the flowing *in vitro* dissolution pattern when measured using a USP type II dissolution apparatus (paddle) according to US Pharmacopeia XXII in 0.05 M phosphate buffer at pH 6.8:

(a) no more than about 15% of the total fluvoxamine is released after 0.5 of an hour of measurement in the apparatus;

(b) no more than about 25% of the total fluvoxamine is released after 1 hour of measurement in the apparatus;

(c) between about 20% and about 75% of the total fluvoxamine is released after 2 hours of measurement in the apparatus;

(d) not less than about 75% of the total fluvoxamine is released after 4 hours

of measurement in the apparatus; and

(e) not less than about 85% of the total fluvoxamine is released after 6 hours of measurement in the apparatus" has been inserted.

The following is an examiner's statement of reasons for allowance:

The closest prior art, Norling, does not teach two populations of fluvoxamine particles coated with different amount of rate-controlling polymeric acrylate, methacrylate lacquer or mixture thereof, to allow controlled release of the fluvoxamine over a period of not less than about 12 hours and specific release profiles as recited in independent claims 47 and 57. The present specification showed that these specific release profiles are obtained from two populations of particles with coating in a concentration ranges from 4%, 6%, 8%, 12% and 15% (tables 10, and 16-18). Norling further does not teach a non-pareil core. The cited references do not suggest combining the two populations of particles to achieve the release profiles that are critical to the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
Art Unit 1618